UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/700,314 | 10/28/2003 | Karl J. Guegler | PF-0025-4 DIV | 5007 |

22428 7590 04/26/2006

FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

| EXAMINER | |
|---|---|
| MERTZ, PREMA MARIA | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1646 | |

DATE MAILED: 04/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/700,314 | GUEGLER ET AL. | |
| | Examiner | Art Unit | |
| | Prema M. Mertz | 1646 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 3/13/06

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 63-77 is/are pending in the application.

4a) Of the above claim(s) 70-71 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 63-69, 72-77 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/15/06
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

1. Amended claims 63, 67-68, (3/13/2006), original claims 64-66, 69, and new claims 75-77 (3/13/2006) are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 3/13/2006 is acknowledged.

3. The following previous objections and rejections are withdrawn in light of applicants amendments filed on 3/13/2006:

(i) the objection to the specification;

(ii) the 35 USC 112, first paragraph, new matter rejection over claims 63-66;

(iii) the 35 USC 112, second paragraph rejection over claims 63-69, 72-74;

Applicant's arguments with respect to claims 63-69, 72-74 have been considered but are moot in view of the new ground(s) of rejection.

(iv) the 35 U.S.C. 112, first paragraph rejection, over claims 63-69 and 72-74, for the recitation of "consisting essentially of";

(v) the 35 U.S.C. 102(b) rejection over claims 63, 66-67, as being anticipated by Osawa et al (U.S. Patent No. 5,126,434); and

(vi) the 35 U.S.C. 103(a) rejection over claims 63, 66-69 as being unpatentable over Osawa et al (U.S. Patent No. 5,126,434) as applied to claims 63, 66-67 above, and further in view of Hart (U.S. Patent No. 5,094,941).

4. Applicant's arguments filed on 3/13/2006 have been fully considered and were persuasive in part. The issues remaining and new issues are restated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim rejections-35 USC § 112, first paragraph***

6a. Claims 63-69, 72-77 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is maintained for reasons of record set forth at pages 5-7 of the previous Office action (10/13/2005).

Applicants argue that with respect to claim 63, the claim has been amended and does not recite "a naturally occurring amino acid sequence at least 90% identical to ...SEQ ID NO:2". However, contrary to Applicants arguments, the rejection was also over the limitation "at least 90% identical to ...SEQ ID NO:2" which encompasses variants of the polypeptide of amino acid sequence set forth in SEQ ID NO:2 as set forth in amended claim 63©. Furthermore, amended claim 63© explicitly recites variants of SEQ ID NO:2 and new claim 77 recites antibody to variants of SEQ ID NO:2 because the claim recites "antibody...which binds to a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a complement polynucleotide of SEQ ID NO:1". However, other than SEQ ID NO:2, Applicants have failed to describe fragments of SEQ ID NO:2, such that fragments of the protein or substitution, deletion, or addition of a single amino acid residue would enable a protein of the biological characteristics of the desired protein. In the instant situation, where the amount of embodiments are innumerable, the enabled embodiment amounts to only the complete amino acid sequence of SEQ ID NO:2. It is also asserted that if applicants were to randomly begin making fragments, the success rate, i.e. those that would have biological activity, would be low. There is little to no

guidance as to which of these other fragments would possess the desired biological activity. The specification provides only primary sequence data (i.e. SEQ ID NO. 2). No secondary or tertiary structure information is provided. Further, if the biological activity belongs to the fragment of the amino acid sequence of SEQ ID NO:2, the specification does not teach either which portion or which amino acids of the sequence are necessary for activity. Additionally, one would expect that fragmentation of a 109 amino acid protein would abolish activity because activity is determined not only by primary sequence, but also three-dimensional structure, as for example, is the case for the ligand binding site of a receptor or for the catalytic site of an enzyme. For these reasons, the specification does not provide adequate written description of the claimed genus of fragments. Therefore only an antibody to an isolated polypeptide molecule comprising the amino acid sequence set forth in SEQ ID NO:2 and equivalent degenerative codon sequences thereof, but not the full breadth of the claims meets the written description provision of 35 USC 112, first paragraph and therefore this rejection is being maintained for reasons of record.

6b. Claims 63-69, 72-77, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated antibody which specifically binds a protein consisting of the amino acid sequence set forth in SEQ ID NO:2 does not reasonably provide enablement for an isolated antibody to a polypeptide variant of SEQ ID NO:2 as recited in claim 63 or a polypeptide variant as recited in claim 77(b). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 7-10 of the previous Office action (10/13/2005).

Applicants argue that the limitation "at least 90% identical to SEQ ID NO:2" has been deleted from the claim 63. However, contrary to Applicants arguments, claim 63© as amended recites variants and new claim 77(b) encompasses an antibody to variants of the polypeptide of SEQ ID NO:2 and therefore this rejection is being maintained for reasons of record.

***Claim rejections-35 USC § 112, second paragraph***

7. Claims 63-69, 72-77 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 63 is vague and indefinite for several reasons.

Claim 1, sub-part(b) recites the limitation "including" and claim 1(c) recites "includes". Which renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 63, 67-68, 75-77, are vague and indefinite because they recite "or other specific binding molecule". It is unclear what the metes and bounds of this term are.

Claim 77 recites "hybridizes under stringent conditions", which is a relative and conditional term and renders the claim indefinite. Furthermore, some nucleic acids, which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. The metes and bounds of the claim thus cannot be

ascertained. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "stringent".

Claims 64-66, 72-74, are rejected as vague and indefinite insofar as they depend on the above rejected claims for their limitations.

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 63-67, 76-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Li et al.(US Patent No. 6,174,995).

Li et al discloses a cDNA encoding MCP-4 polypeptide, which has chemotactic activity (see abstract and Figure 8). The reference also teaches various antibodies to the MCP-4 polypeptide (see column 15, lines 44-67; column 16, lines 1-9). Therefore, the antibody of the reference meets the limitations of (1) an antibody to a variant of SEQ ID NO:2 as recited in claim 63© and (2) an antibody to a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a complement polynucleotide of SEQ ID NO:1, wherein the polypeptide has chemotactic activity as recited in claim 77, because the polynucleotide of the

reference would hybridize under stringent conditions to the complement of SEQ ID NO:1. Therefore, the antibody disclosed in the reference meets the limitations of claims 63-67, 76-77.

***Claim Rejections - 35 USC § 103***

9. Claims 63, 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al.(US Patent No. 6,174,995) as applied to claims 63-67, 76-77 above, and further in view of Hart (U.S. Patent No. 5,094,941).

Li et al teaches an antibody to a chemotactic protein (see paragraph 8 above) except that Li does not explicitly teach the labeled antibody.

Hart teaches a means of labeling antibodies with radioisotopes or imaging agents and enzymes (as conjugates) for diagnostic purposes (including combinations with pharmaceutical carriers for administration of labeled material) or for use in immunoassay methods, respectively (at column 13, paragraphs 2 and 3, lines 25-61). Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the antibody of Li in view of Hart by labeling antibodies by the method of Hart because labeled antibody administration coupled with radiographic analysis (imaging) is useful for in vivo diagnostic purposes.

***Claim rejections-Double Patenting***

***Non-statutory double patenting rejection (obviousness-type)***

10. The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy

reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and 8 may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 63-69, 72-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,692,920 ('920). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-4 of U.S. Patent No. '920 (having all common inventors with the instant application), claims an antibody to a polypeptide of SEQ ID NO:2. In instant claims 63-69, 72-77, an antibody that specifically binds to a polypeptide of SEQ ID NO:2 is claimed. The patented claims 1-4 are generic to claims 63-69, 72-77 in the present application and encompasses subject matter to which the instant claims are a species because the antibody as recited in instant claims 63-69, 72-77 is encompassed by the claims of the patent. However, the instant claims are obvious from the patented claims because the instant claim are directed to specific embodiments

encompassed by the patented claims. The instant product is included in the patented claims 1-4. It would have been obvious to one of ordinary skill in the art at the time the present invention was made, that an antibody to a polypeptide of SEQ ID NO:2 included an antibody, which specifically binds SEQ ID NO:2. The patented claims if infringed upon would also result in infringement of the claims of the instant application. Allowance of the pending claim, therefore, would have the effect of extending the enforceable life of the allowed claims beyond the statutory limit.

***Conclusion***

No claims are allowed.

Claims 63-69, 72-77 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
April 11, 2006